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ATTN.: *Commisioner for Patents*

FROM: *Nazir Khan, M.D.*

RE: ***(PAGES 29-58)*** *APPEAL BRIEF for APP. No.: 10/812,380*

FAX #: *571-273-8300*

DATE: *5/26/2009* *PAGES:* *30*

◊ *URGENT*

◊ *REPLY ASAP*

◊ *PLEASE RESPOND/COMMENT*

◊ *PLEASE REVIEW*

◊ *FOR YOUR INFORMATION*

Comments:

1. (amended, appealed) An arteriovenous shunt comprising:

a. an arterial graft comprising a body, a lead end and a terminal end, said lead end being configured for subcutaneous connection to an artery by anastomosis, wherein said arterial graft has a first diameter; and

b. a single lumen venous outflow catheter comprising an intake end and depositing end, said depositing end being configured for insertion through a vein into the right atrium of the heart, wherein said venous outflow catheter has a second diameter different from said first diameter; and

c. a cylindrical cuff operable to direct passage of blood from said arterial graft to said venous outflow catheter, said cuff comprising an inlet in blood communication with an outlet:

i. said inlet being disposed about and connected to said terminal end of said

arterial graft; and

ii. said outlet being disposed about and connected to said intake end of said

venous outflow catheter; wherein said cuff provides a secure fit for

said arterial graft first diameter and said venous outflow catheter second diameter.

2. (previously presented, appealed) The arteriovenous shunt of claim 1 wherein said arterial graft

is made of a biocompatible flexible material.

3. (amended, appealed) The arteriovenous shunt of claim 2, wherein said biocompatible

flexible material is polytetrafluoroethylene(PTFE) or other biocompatible material

4. (appealed) The arteriovenous shunt of claim 1, wherein said arterial graft has a

diameter from about 2 mm to about 8 mm and a length from about 20 cm to about 60 cm.

5. (appealed) The arteriovenous shunt of claim 4, wherein said arterial graft has a diameter of from about 6 mm to about 8 mm and a length of about 40 cm.

6. (appealed) The arteriovenous shunt of claim 1, wherein said artery is the brachial, axillary, femoral or external iliac artery.

7. (Appealed) The arteriovenous shunt of claim 1, wherein said cuff is polytetrafluoroethylene or polyethylene terephthalate.

8. (Appealed) The arteriovenous shunt of claim 1, wherein said venous outflow catheter has a diameter from about 1 mm to about 7 mm and a length of from about 20 cm to about 80 cm.

9. (Appealed) The arteriovenous shunt of claim 1, wherein said venous outflow catheter has a diameter from about 5 mm to about 7 mm and a length of from about 40 cm to

about 60 cm.

10. (amended, appealed) The arteriovenous shunt of claim 1, wherein said venous outflow catheter is made of other biocompatible materials.

11. (appealed) The arteriovenous shunt of claim 1, wherein said vein is the cephalic, axillary, jugular, femoral or external iliac vein.

12. (previously presented, appealed) The arteriovenous shunt of claim 1, wherein said venous outflow catheter has a diameter of about 1 mm smaller than said arterial graft.

13. (amended, appealed) A system for performing hemodialysis on a patient comprising: a. an arteriovenous shunt comprising:

i. an arterial graft comprising a body, a lead end and a terminal end, said lead end being configured for subcutaneous connection to an artery by anastomosis, wherein said arterial graft has a first diameter; and

ii. a single lumen venous outflow catheter comprising an intake end and

depositing end, said depositing end being configured for insertion through a

vein into the right atrium of the heart, wherein said venous outflow catheter

has a second diameter different from said first diameter; and

iii. a cylindrical cuff operable to direct passage of blood from said arterial graft

to said venous outflow catheter, said cuff comprising an inlet with blood

communication with an outlet:

1. said inlet being disposed about and connected to said terminal end of

said subcutaneous graft; and

2. said outlet being disposed about and connected to said intake end of

said venous outflow catheter; wherein said cuff provides a secure fit for said arterial graft first diameter and said venous outflow catheter second diameter;

14. (previously presented, appealed) The system according to claim 13, wherein said venous outflow catheter has a diameter of about 1 mm smaller than said arterial graft.

15. (original, appealed) The system according to claim 13, wherein said artery is the brachial, axillary, femoral or external iliac artery.

16. (original, appealed) The system according to claim 13, wherein said vein is the cephalic, axillary, jugular, femoral or external iliac vein.

17. (amended, appealed) A method of performing hemodialysis on a patient comprising:

a. surgically inserting an arteriovenous shunt into a patient, wherein said arteriovenous shunt comprises:

i. an arterial graft comprising a body, a lead end and a terminal end, said lead end being configured for subcutaneous connection to an artery by anastomosis, wherein said arterial graft has a first diameter; and

ii. a single lumen venous outflow catheter comprising an intake end and

depositing end, said depositing end being configured for insertion through a

vein into the right atrium of the heart, wherein said venous outflow catheter

has a second diameter different from said first diameter; and

iii. a cylindrical cuff operable to direct passage of blood from said arterial graft

to said venous outflow catheter, said cuff comprising an inlet in blood

communication with an outlet:

1. said inlet being disposed about and connected to said terminal end of

said arterial graft; and

2. said outlet being disposed about and connected to said intake end of

said venous outflow catheter, wherein said cuff provides a secure fit for said arterial graft first

diameter and said venous outflow catheter second diameter;

b. connecting said arterial graft to a hemodialysis apparatus;

c. collecting blood from the patient through said arterial graft;

d. passing said blood through the hemodialysis apparatus;

e. collecting purified blood from hemodialysis apparatus; and

f. transmitting said purified blood through said cuff into said venous outflow catheter which is located in the right atrium and the blood is directly deposited into the right atrium.

18. (previously presented, appealed) The method according to claim 16 wherein said venous outflow catheter has a diameter of about 1 mm smaller than said arterial graft.

19. (original, appealed) The method according to claim 16, wherein said artery is the brachial,

axillary, or femoral, external iliac artery.

20. (original, appealed) The method according to claim 16, wherein said the vein is the axillary, jugular, femoral or external iliac vein.

IX) Evidence Appendix: Copy of the declaration of oath with exhibit 1 and 2 are attached.

Declaration in Support of Application

1. We are the applicants in the above identified patent application

2.We declare the HERO™ (Hemodialysis Reliable Outflow) vascular access device, manufactured by Hemisphere Inc. company is a hemodialysis arteriovenous shunt identical to the applicants claimed invention. Clinical studies revealed new and unexpected results.

These results are a marked decrease in bacteremia rate versus currently used cuffed tunneled dialysis catheters and current arteriovenous graft literature.

Improved adequacy of dialysis and patency versus currently used cuffed tunneled dialysis catheters.

Please see Exhibit 1 and Exhibit 2 as supporting documents for the HERO™ device.

In patients with central venous occlusion, the HERO™ device has achieved a success rate for allowing dialysis in patients with no other option, 96.2% of the time (50/52 patients).

3. I declare that all of the statements made herein of my knowledge are true and that all statements made upon information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment , or both, under Section 1001 of Title 18 of United

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IX) Evidence Appendix: Copy of the declaration of oath with exhibit 1 and 2 are attached.

X) Related Proceedings Appendix

The copies of the court decisions are attached

Exhibit 1 Appeal Brief for App. No.: 10/812,380 (IX) Evidence Appendix

Kuhlmann, H. HeRO Vascular Access Device: A New Long-Term Dialysis Access Option for Access-Challenged Patients 9CVS March 2008	**Objective:** The purpose of the study was to assess HeRO bacteremia and patency rates, adequacy of dialysis, and adverse events in graft-eligible and in "access challenged" subjects i.e., catheter dependent and poor venous outflow subjects. **Methods:** The HeRO device consists of a 6 mm inner diameter (ID) ePTFE upper arm graft attached with a titanium connector that is surgically coupled to a subcutaneous 8 mm ID nitinol reinforced silicone outflow catheter, designed to bypass peripheral stenosis and exit into the right atrium via the IJ vein. Ninety HeRO subjects were enrolled in two study arms—access challenged (catheter only and graft-eligible (graft only) subjects. Study endpoints included bacteremia and patency rates, adequacy of dialysis and adverse events. All events were compared to historical controls. **Results:** The data showed a marked decrease in the HeRO-related bacteremia rate in both study arms. The catheter arm HeRO-related bacteremia rate was 0.12/1,000 days versus U tunneled dialysis catheter (TDC) literature rate of 2.3/1,000 days. The graft arm HeRO-related bacteremia rate was 0.16/1,000 days versus graft literature rate of 0.31/1,000 days. HeRO patency rates (primary, primary-assisted, secondary and functional) in both study arms were better than TDC literature and equivalent to graft literature. HeRO adequacy of dialysis data (spKt/V 1.6-1.7) surpasses TDC literature (spKt/V 1.20-1.40) and was comparable to graft literature (spKt/V 1.37-1.67). Serious device/procedure-related adverse events were comparable to both TDC and graft literature. **Conclusions:** The HeRO device may be the best long-term access alternative for access challenged patients including those that are catheter dependent, are losing fistulas and grafts due to venous obstructions, have poor anatomy for a fistula or graft, or are receiving home-based dialysis via a TDC.
Work, J. New Vascular Access Device Option for Catheter Dependent Patients ASDIN February 2008	**Purpose:** The purpose of this study was to evaluate catheter-dependent patients dialyzing with a new long-term access option, the Hemodialysis Reliable Outflow (HeRO™) vascular access device for device/implant procedure-related bacteremias compared to clinical tunneled dialysis catheter literature rates. HeRO is entirely subcutaneous and consists of a 6 mm inner diameter ePTFE upper arm graft connected to a 8 mm inner diameter nitinol-reinforced silicone outflow catheter that empties into the central venous system eliminating the need for graft to vein anastomosis, thus bypassing peripheral venous stenosis. **Methods:** This was a multi-center FDA regulated study designed on the premise that subjects considered catheter-dependent or poor candidates for fistula or graft due to inadequate venous outflow would experience a significant reduction in bacteremia rates with the HeRO device compared to a tunneled dialysis catheter. **Results:** The 39 subjects enrolled had on average 4.2 previous TDCs (range 1-16) and 1.7 previous bacteremias (range 1-4). As of 10/2007, 5,460 HeRO days have accumulated with an average of 7.3 months of HeRO follow-up. The overall HeRO device/procedure-related bacteremia rate was 0.55/1,000 days compared to the catheter literature

10:15 am - 11:00 am **SCIENTIFIC SESSION 4 – DIALYSIS**

Moderated by: Joann M. Lohr, MD & Anil Hingorani, MD

Learning Objectives:
- Describe recent trends in outcomes for arteriovenous access procedures
- Recognize evolving strategies to improve treatment planning for arteriovenous access procedures
- Identify novel strategies to enhance outcomes for arteriovenous access procedures in patients with challenging venous anatomy

MP14. Hemoaccess Placement in patients with Challenging Central Vein Occlusion
Chris Stout, MD, Jean Panneton, MD, Marc H. Glickman, MD. Eastern Virginia Medical. Norfolk. VA, USA.

December 12, 2008

Hemoaccess Placement in patients with Challenging Central Vein Occlusion

Back to Annual Meeting
Back to Program

Chris Stout, MD, Marc H. Glickman, md, Jean Panneton, MD.
Eastern Virginia Medical, Norfolk, VA, USA.

OBJECTIVES: The placement of hemoaccess devices in patients with central vein occlusion is becoming more challenging for surgeons. The incidence of catheter dependent patients on dialysis continues to rise. Catheter dependent dialysis is fraught with complications including higher morbidity and mortality when compared to conventional dialysis. The purpose of the abstract is to present experience with the HeRO access device, which returns the patient to a conventional graft like access.
METHODS: The HeRO device, a graft with a central outflow component designed to bypass central venous stenosis, consists of ePTFE upper arm graft fitted with a titanium connector that is surgically coupled to a subcutaneous nitinol silicone outflow component which exits into the central venous system. Prospective data included average number of prior access procedures, the degree and type of central vein occlusion, vessel anatomy and surgical implant location.
RESULTS: Fifty two patients have undergone attempted placement of the HeRO devic. Forty patients have had placement of the device after successful angioplasty of near central vein occlusion, four patients have had placement of the device within the subclavian veins with central vein angioplasty, one patient had placement of the device into the SVC through

a retroperitoneal approach for SVC and IVC occlusion, two patients had placement into large azygous veins, four patients had placement through recannalized central veins and internal jugular veins and two patients had unsuccessful placement attempts due to inability to recannalize the central veins. Fifty patients have had successful placement of this device and of these forty-eight patients have had successful conversion from catheter dependent dialysis to conventional dialysis

CONCLUSIONS: HeRO is the first AV access device to offer significant alternative to patients who are catheter dependent for their dialysis due to central vein pathology. These are very complex and demanding patients. HeRo device offers a promising alternative for these patients allowing conventional dialysis to be achieved

Tuesday, March 17

X) Related Proceedings Appendix

The copies of the court decisions are attached

HeRO™ Vascular Access Device: A Long Term Solution for Access-Challenged Patients.

Howard Katzman MD

Notes

INTRODUCTION

Tunneled dialysis catheters (TDCs) are considered the last resort "long-term" vascular access option compared to arteriovenous fistulas (AVFs) and grafts (AVGs). TDCs cause a high incidence of catheter-related bacteremia because the TDC penetrates the skin barrier creating a route for contamination; TDC-related bacteremias increase patient morbidity and mortality and result in significantly increased hospital costs.[1] TDCs deliver less effective dialysis due to reduced blood flow rates and are plagued with frequent malfunctions. [2-4] Additionally, traditional TDCs may induce central venous stenosis, which can limit future AVF or AVG options.[5] Despite these disadvantages and the success of the Fistula First Initiative, the number of patients dialyzing on TDCs continues to increase. As outlined in the DOPPS studies, the number of prevalent patients dialyzing on catheters virtually doubled from 15.2% in 1996-97 to 28.2% in 2002-2003[6] and as recently as 2006-2007, the End Stage Renal Disease Clinical Performance Measure Project (ESRD CPM project) noted a 2% increase in TDC catheter prevalence. Furthermore, over 70% of ESRD patients initiate dialysis with a catheter.[7]

Tunneled catheter dependency as a result of central venous stenosis, which inhibits peripheral access placement, can be significantly decreased by implantation of the HeRO™ Vascular Access Device. The FDA has cleared the HeRO™ device for maintaining vascular access in those patients who have exhausted all other peripheral access options. This device combines the functional status of an ePTFE graft and tunneled catheter into a permanently implanted subcutaneous access. The HeRO™ device consists of a 6 mm inner diameter (ID) ePTFE graft component fitted with a titanium connector that is surgically coupled at the time of implant to a subcutaneous 5 mm ID braided nitinol reinforced silicone outflow component designed to bypass peripheral stenosis and exit into the superior vena cava/right atrial junction via the internal jugular (IJ) vein, see Figure 1 and Figure 2. The outflow component is introduced into the IJ vein using standard Seldinger technique and tunneled subcutaneously to the delta/pectoral groove in the shoulder area. The HeRO™ ePTFE graft is then tunneled from the shoulder area to the lower portion of the upper arm just above the elbow. The outflow component is then connected to the graft via the silicone encapsulated titanium connector and lastly, a graft to brachial artery anastomosis is created in the same manner as a conventional upper arm ePTFE graft. The HeRO™ device requires a heal-in period to allow the ePTFE to incorporate into the surrounding tissue before it can be accessed. During this time, a patient may require a bridging TDC for dialysis. Once the HeRO™ device is ready for cannulation (per K/DOQI graft cannulation guidelines), it is accessed in the same manner as a conventional graft eliminating the need for special training at dialysis centers.

Syllabus

NOTE: Where it is feasible, a syllabus (headnote) will be released, as is being done in connection with this case, at the time the opinion is issued. The syllabus constitutes no part of the opinion of the Court but has been prepared by the Reporter of Decisions for the convenience of the reader. See *United States* v. *Detroit Timber & Lumber Co.*, 200 U. S. 321, 337.

SUPREME COURT OF THE UNITED STATES

Syllabus

KSR INTERNATIONAL CO. *v.* TELEFLEX INC. ET AL.

CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

No. 04–1350. Argued November 28, 2006—Decided April 30, 2007

To control a conventional automobile's speed, the driver depresses or releases the gas pedal, which interacts with the throttle via a cable or other mechanical link. Because the pedal's position in the footwell normally cannot be adjusted, a driver wishing to be closer or farther from it must either reposition himself in the seat or move the seat, both of which can be imperfect solutions for smaller drivers in cars with deep footwells. This prompted inventors to design and patent pedals that could be adjusted to change their locations. The Asano patent reveals a support structure whereby, when the pedal location is adjusted, one of the pedal's pivot points stays fixed. Asano is also designed so that the force necessary to depress the pedal is the same regardless of location adjustments. The Redding patent reveals a different, sliding mechanism where both the pedal and the pivot point are adjusted.

In newer cars, computer-controlled throttles do not operate through force transferred from the pedal by a mechanical link, but open and close valves in response to electronic signals. For the computer to know what is happening with the pedal, an electronic sensor must translate the mechanical operation into digital data. Inventors had obtained a number of patents for such sensors. The so-called '936 patent taught that it was preferable to detect the pedal's position in the pedal mechanism, not in the engine, so the patent disclosed a pedal with an electronic sensor on a pivot point in the pedal assembly. The Smith patent taught that to prevent the wires connecting the sensor to the computer from chafing and wearing out, the sensor should be put on a fixed part of the pedal assembly rather than in or on the pedal's footpad. Inventors had also patented self-contained modular sensors, which can be taken off the shelf and attached to any

702 F2d 989 In Re Howard Sernaker

702 F.2d 989

217 U.S.P.Q. 1

In re Howard SERNAKER.

Appeal No. 82-579.
Serial No. 916,018.

United States Court of Appeals,
Federal Circuit.

Feb. 28, 1983.

Michael F. Petock, Philadelphia, Pa., argued and filed briefs for appellant.

Associate Sol. Fred W. Sherling, Washington, D.C., argued for Patent and Trademark Office. With him on th
Sol., Joseph F. Nakamura, Washington, D.C.

Before DAVIS, Circuit Judge, COWEN, Senior Circuit Judge, and NICHOLS, Circuit Judge.

NICHOLS, Circuit Judge.

1

This case is before us on appeal from the decision of the Patent and Trademark Office Board of Appeals (bo
decision, the board affirmed the examiner's rejection, under 35 U.S.C. Sec. 103, of claims 1-6 and 8-11 in
application serial No. 916,018, filed June 15, 1978, entitled "Embroidered Transfer and Method of Making."
comprise all the claims in the case. We reverse.

2

* Background

A. The Invention

3

Appellant has invented a type of embroidered emblem and a method of making the same. Claims 1 and 10,
independent claims in appellant's application, are representative of the method and of the emblem, respecti

4

1. A method of making an embroidered transfer or emblem comprising the steps of:

5

(a) embroidering a pattern on a portion of a substrate while using thread free from oil and with said thread
single color and in an amount so that a portion of the pattern is sculptured by having a greater thickness th
portion of the pattern,

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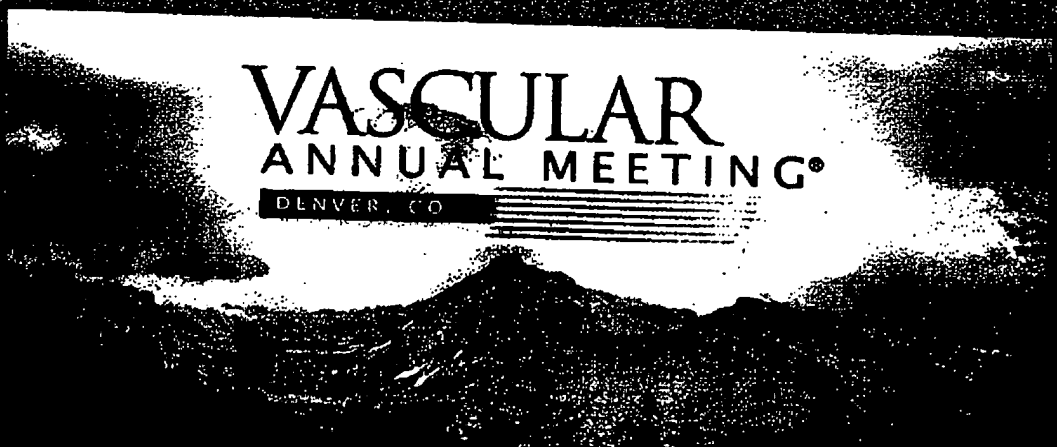
Abstracts of the 2009 Vascular Annual Meeting® The Society for Vascular Surgery



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Author Disclosures: J. Vos, None; G.J. De Borst, None; T.T.C. Overtoom, None; J.P.M. de Vries, None; B.D.W. van de Pavoordt, None; P. Zanen, None; R.G.A. Ackerstaff, None.

Dialysis Access, Education/ Training Credentialing

PP20.

Early Commercialization Experience with New Long Term Vascular Access for Catheter-Dependent Patients

Howard E Katzman. University of Miami Hospital, Miami, FL

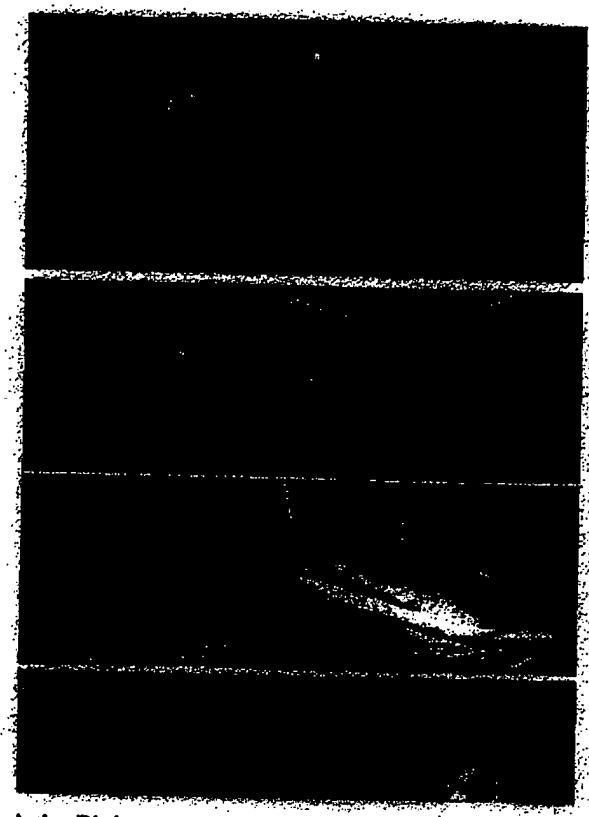
Objectives: The purpose of this abstract is to report early commercialization experience with the HeRO™ Vascular Access Device, a new long-term dialysis access device approved by FDA for "access challenged" patients i.e., catheter-dependent or patients that are poor candidates for fistulas or grafts due to venous obstruction. The HeRO™ device is designed to provide a graft-like vascular access and lower bacteremia rates than a tunneled dialysis catheter.

Methods: The HeRO™ device, a graft with central outflow designed to bypass peripheral stenosis, consists of an ePTFE upper arm graft fitted with a titanium connector that is surgically coupled to a subcutaneous nitinol reinforced silicone outflow catheter which exits into the right atrium via the internal jugular vein. Procedural data has been captured on 60 early commercialization patients implanted with the HeRO™ device including access and medical history and device-implant success.

Results: To-date, data has been captured on 60 patients (mean age 58.9; 45.3% male; 55.0% diabetic) with a history of 4.1 years on dialysis, a mean 5.0 previous catheters, 2.2 previous grafts, and 1.5 previous fistulas and 3.6 mean previous bacteremias (range 1-17). The HeRO™ device was successfully implanted in all subjects using a variety of interventional techniques, although 60.0% percent had evidence of hemodynamically significant central venous stenosis.

Conclusion: This data demonstrates that access-challenged patients with challenging anatomy and central venous stenosis may be eligible for an alternative long-term vascular access device offering lower bacteremia rates compared to a tunneled dialysis catheter.

Author Disclosures: H.E. Katzman, Participating in HeRO commercialization registry on behalf of Hemosphere, Inc and receiving nominal research grant to complete case report forms as investigator in registry.



Author Disclosures: K. Woo, None; P.R. Cook, None; R.J. Hye, None; T.G. Canty, None.

PP21.

Reduction and Reconstruction of Aneurysmal Arteriovenous Fistulas: Mid-Term Results of a Novel Approach to Salvage Autogenous Dialysis Access

Karen Woo[1], Patrick R Cook[1], Robert J Hye[2], Timothy G Canty[2]. [1]Scripps Green Hospital, La Jolla, CA; [2]Kaiser Permanente Medical Group, San Diego, CA

Background: Over the last decade, K-DOQI guidelines have increasingly emphasized the importance of autogenous arteriovenous fistulas (AVF) for dialysis access. A complication of AVF is aneurysmal dilatation with a subset developing massive diffuse aneurysm. Treatment of massive aneurysmal AVF generally involves either ligation or resection with use of prosthetic interposition. In order to maintain an all-autogenous access, we developed a procedure to treat massive aneurysmal AVF in which the lumenal diameter is reduced, excess length is resected, and the new reconstructed AVF is retunneled for continued use.

Methods: Over a 4 year period, the reduction/revision procedure was performed on 18 patients with an AVF diameter of 4-7cm. Indications for operation were thrombosis, skin breakdown, infection, bleeding, and/or poor flow. Revision was performed by resecting redundant length, reducing diameter, and then reconstructing the fistula.

Results: Patients ranged in age from 25 to 83 with a mean of 48. There were 12 men and 6 women. The mean and median follow-up was 20 months. The mean and median primary patency was 17 and 14 months, respectively. The mean and median secondary patency was 19 and 16.5 months, respectively. Two patients died, one AVF thrombosed, and two were ligated secondary to infection. One fistula developed a stenosis that was treated with angioplasty. There are no recurrent aneurysms to date.

Conclusions: Surgical resection of excess length, reduction of lumenal diameter, and reconstruction is a viable option for the treatment of complicated massive diffusely aneurysmal AVF. This technique offers the ability to maintain the benefits of an all autogenous dialysis access while conserving future dialysis sites.

PP22.

Report of the First Vascular Surgery In-Training Examination (VSITE)

Amy B Reed[1], Robert S Rhoder[2], Thomas W Biester[2], John J Ricotta[3]. [1]University of Cincinnati, Cincinnati, OH; [2]American Board of Surgery, Philadelphia, PA; [3]Washington Hospital Center, Washington, DC

Background: As Vascular surgery training has evolved from a single clinical year following general surgery training to a multi year training program with independent certification, the need for an in-training examination to assess the preparedness of the candidate for the certification process has become apparent. Our objective is to analyze the psychometric characteristics of the first Vascular Surgery In-Training Examination (VSITE) and to correlate performance on the VSITE with performance on the Qualifying Examination (QE) in Vascular Surgery.

Methods: The Vascular Surgery Board (VSB) in conjunction with the Association of Program Directors in Vascular Surgery (APDVS) appointed a panel to develop the VSITE which was administered by the Vascular Surgery Board of the American Board of Surgery(VSB/ABS). Thirty-one APDVS and SVS members contributed questions in clinical and basic science areas of vascular surgery training. All questions were again reviewed by the panel and the VSB /ABS prior to administration of the examination. The psychometric characteristics of the examination and correlation of performance on VSITE and VQE were undertaken by ABS staff.

Results: On February 16, 2008, 240 examinees took the initial Vascular Surgery In-Training Examination online through a secure, proctored website. This total included 216 vascular residents from 91 of 95 (96%) training programs. The psychometric properties of the examination were excellent with index values comparable to other ABS examinations. The average difficulty value for all items was 76.6%, the average discrimination value was 0.20, the total test reliability coefficient was 0.85 and the standard error of measurement was 2.9% correct. Scores ranged from 55% to 93% correct with an average of 76.7% correct. Sixty-four candidates took both the VSITE and the VQE in 2008. A high correlation of 0.70 was noted between

EXPANDED POLYTETRAFLUOROETHYLENE (PTFE) SUBCUTANEOUS ARTERIOVENOUS CONDUIT: AN IMPROVED VASCULAR ACCESS FOR CHRONIC HEMODIALYSIS

L. D. Baker, Jr., J. M. Johnson, and D. Goldfarb

Recent experience with expanded polytetrafluoroethylene (PTFE) has demonstrated that a specific form of this material functions extremely well as a small artery prosthesis[1]. The basic ultrastructure of expanded PTFE is illustrated in Figure 1. Spindle-shaped PTFE nodes are oriented radially in the graft wall and these nodes are interconnected by fine fibrils. This node-fibril arrangement forms a type of lattice-work, and the distance between the nodes as well as the node diameter can be varied in the fabrication process. The specific form of this material which gave the most favorable results in regards to controlled tissue ingrowth and long-term patency has the following characteristics: 1) an internodal distance of 20 to 30 μ, 2) a node diameter of less than 12 μ, 3) a wall thickness of between 0.3 and 0.5 mm, and 4) a density of 0.3 Gm/ml. Histological evaluation of these grafts revealed a thin neointima with flattened nucleated endothelial cells facing the bloodstream, along with complete and uniform transmural fibrous tissue ingrowth and intramural neocapillaries.

With the early clinical success of expanded PTFE as a femoral-popliteal artery bypass graft[2], we then considered the use of this material as a subcutaneous A-V conduit for chronic hemodialysis.

Prior to any clinical trial, however, several questions needed to be answered:

1) Could the material withstand repeated percutaneous large bore punctures?
2) Following withdrawal of the dialysis catheter would there be a reasonable and prompt cessation of bleeding?
3) Would clot propogation at the puncture site lead to obstruction of the graft?
4) Would infection of the prosthetic material become a prohibitive problem?

MATERIALS AND METHODS

Experimental. Seven grafts of expanded PTFE* were then inserted into dogs as loop fistulae between the common femoral artery and common femoral vein. Over the following 8 wks, mock dialyses were performed weekly for 4 hrs in each of these dogs with a #14 gauge Medicut catheter. These catheters were inserted percutaneously into the graft, and blood was returned to the animal through a vena puncture in the cephalic vein of the foreleg. The animals were sacrificed after the 8 wk period and the grafts examined grossly and histologically.

Clinical. From April of 1975 through February 1976, 72 patients at the Good Samaritan Hospital Kidney Center and Maricopa County General Hospital Dialysis Unit, Phoenix, Arizona, have been dialyzed using the expanded PTFE subcutaneous A-V conduit (Table I). Forty-three of these patients are male and 29 female. The ages of these patients range from 19 to 73 yrs, with a mean age of 46 yrs. Our preferred method of placement has been what we term the straight forearm graft, which is an anastomosis of the graft to the distal radial artery and to the cephalic vein near the antecubital fossa. If, however, the radial artery is not satisfactory either due to insufficient flow or prior access use, a loop fistula is constructed in the forearm between the brachial artery and cephalic vein. If access sites are not available in the upper extremities, then we have implanted these grafts in the thigh, either as a straight graft between the superficial femoral artery and common femoral vein, or as a loop fistula between the common femoral artery and common femoral vein.

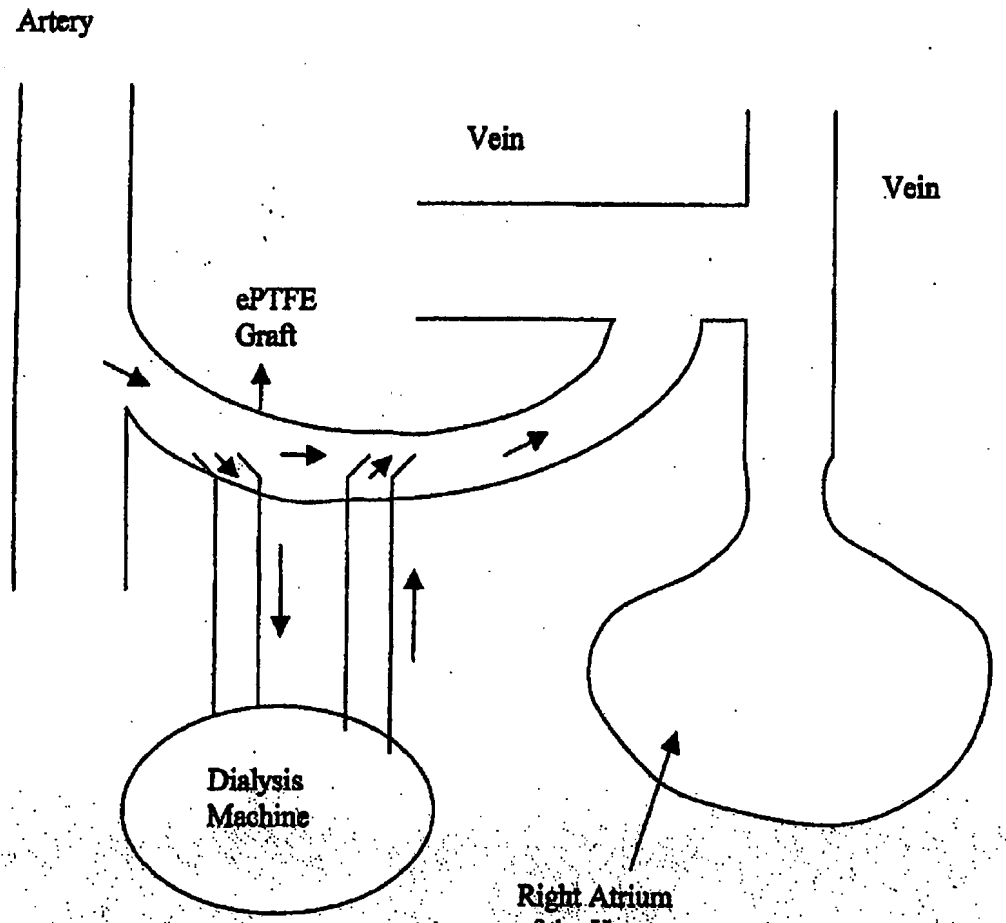
TABLE I

EXPERIENCE WITH PTFE A-V FISTULAS

No. of Patients	72
Male	43
Female	29
No. of Grafts	84
Forearm, straight	48
Forearm, loop	16
Thigh, straight	6
Thigh, loop	13
Arm, straight	1
Age Distribution (yrs)	
10-19	1
20-29	11
30-39	13
40-49	13
50-59	19
60-69	11
70-79	4

We have placed a total of 84 grafts in these 72 patients with 48 in the straight forearm position, 16 as forearm loops, 6 as straight thigh grafts, 13 as thigh loops, and one as a straight arm graft, from the brachial artery at the antecubital fossa to the cephalic vein in the delto-pectoral groove. The majority of these grafts have been 8 mm in diameter, with 10 being 6 mm in diameter. Most of these grafts have been used within 3 days of implantation and several have been employed within 3 hrs. The period of observation has ranged from 4 to 60 wks.

From the Arizona State University-St. Joseph's Hospital Biomedical Engineering Research and Education Program, and Good Samaritan Hospital, Phoenix, Arizona.
Supported in part by The Robert and Irene Flinn Foundation.
*Impra graft, International Medical Prosthetic Research Associates, Inc., 4209 South 36th Place, Phoenix, Arizona.



BITTNER ARTERIOVENOUS SHUNT – (1976)
Subcutaneous with ePTFE conduit

FIG. 4

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2144.04 Legal Precedent as Source of Supporting Rationale [R-1] - 2100 Patentability

2144.04 Legal Precedent as Source of Supporting Rationale [R-1]

As discussed in MPEP § 2144, if the facts in a prior legal decision are sufficiently similar to those in an application under examination, the examiner may use the rationale used by the court. Examples directed to various common practices which the court has held normally require only ordinary skill in the art and hence are considered routine expedients are discussed below. If the applicant has demonstrated the criticality of a specific limitation, it would not be appropriate to rely solely on case law as the rationale to support an obviousness rejection.

I. AESTHETIC DESIGN CHANGES

In re Seid, 161 F.2d 229, 73 USPQ 431 (CCPA 1947) (Claim was directed to an advertising display device comprising a bottle and a hollow member in the shape of a human figure from the waist up which was adapted to fit over and cover the neck of the bottle, wherein the hollow member and the bottle together give the impression of a human body. Appellant argued that certain limitations in the upper part of the body, including the arrangement of the arms, were not taught by the prior art. The court found that matters relating to ornamentation only which have no mechanical function cannot be relied upon to patentably distinguish the claimed invention from the prior art.). But see *In re Dembiczak*, 175 F.3d 994, 50 USPQ2d 1614 (Fed. Cir. 1999) (The claims of a utility application, drawn to a generally round, orange plastic trash bag with a jack-o-lantern face, were rejected under 35 U.S.C. 103. However, the court reversed the rejection for lack of motivation to combine conventional trash bags with a reference showing a jack-o-lantern face on an orange paper bag stuffed with newspapers.); *Ex parte Hilton*, 148 USPQ 356 (Bd. App. 1965) (Claims were directed to fried potato chips with a specified moisture and fat content, whereas the prior art was directed to french fries having a higher moisture content. While recognizing that in some cases the particular shape of a product is of no patentable significance, the Board held in this case the shape (chips) is important because it results in a product which is distinct from the reference product (french fries).).

II. ELIMINATION OF A STEP OR AN ELEMENT AND ITS FUNCTION

A. Omission of an Element and Its Function Is Obvious If the Function of the Element Is Not Desired

Ex parte Wu, 10 USPQ 2031 (Bd. Pat. App. & Inter. 1989) (Claims at issue were directed to

establish patentability in a claim to an old process so scaled." 531 F.2d at 1053, 189 USPQ at 148.).

In *Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), *cert. denied*, 469 U.S. 830, 225 USPQ 232 (1984), the Federal Circuit held that, where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device.

B. Changes in Shape

In re Dailey, 357 F.2d 669, 149 USPQ 47 (CCPA 1966) (The court held that the configuration of the claimed disposable plastic nursing container was a matter of choice which a person of ordinary skill in the art would have found obvious absent persuasive evidence that the particular configuration of the claimed container was significant.).

C. Changes in Sequence of Adding Ingredients

Ex parte Rubin, 128 USPQ 440 (Bd. App. 1959) (Prior art reference disclosing a process of making a laminated sheet wherein a base sheet is first coated with a metallic film and thereafter impregnated with a thermosetting material was held to render *prima facie* obvious claims directed to a process of making a laminated sheet by reversing the order of the prior art process steps.). See also *In re Burhans*, 154 F.2d 690, 69 USPQ 330 (CCPA 1946) (selection of any order of performing process steps is *prima facie* obvious in the absence of new or unexpected results); *In re Gibson*, 39 F.2d 975, 5 USPQ 230 (CCPA 1930) (Selection of any order of mixing ingredients is *prima facie* obvious.).

V. MAKING PORTABLE, INTEGRAL, SEPARABLE, ADJUSTABLE, OR CONTINUOUS

A. Making Portable

In re Lindberg, 194 F.2d 732, 93 USPQ 23 (CCPA 1952) (Fact that a claimed device is portable or movable is not sufficient by itself to patentably distinguish over an otherwise old device unless there are new or unexpected results.).

B. Making Integral

In re Larson, 340 F.2d 965, 968, 144 USPQ 347, 349 (CCPA 1965) (A claim to a fluid transporting vehicle was rejected as obvious over a prior art reference which differed from the prior art in claiming a brake drum integral with a clamping means, whereas the brake disc and clamp of the prior art comprise several parts rigidly secured together as a single unit. The court affirmed the rejection holding, among other reasons, "that the use of a one piece construction instead of the structure disclosed in [the prior art] would be merely a matter of obvious engineering choice."); but see *Schenck v. Nortron Corp.*, 713 F.2d 782, 218 USPQ 698 (Fed. Cir. 1983) (Claims were directed to a vibratory testing machine (a hard-bearing wheel balancer) comprising a holding structure, a base structure, and a supporting means which form "a single integral and gaplessly continuous piece." Nortron argued that the invention is just making integral what had been made in four bolted pieces.

in Re Leonard R. Kahn., 441 F.3d 977 (Fed. Cir. 2006)

Federal Circuits, Fed. Cir. (March 22, 2006)

Docket number: 04-1616

PTO

U.S. Supreme Court

GRAHAM v. JOHN DEERE CO., 383 U.S. 1 (1966)

383 U.S. 1

GRAHAM ET AL. v. JOHN DEERE CO. OF KANSAS CITY ET AL.
CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE EIGHTH CIRCUIT.

Argued October 14, 1965
Decided February 21, 1966. *

[Footnote *] Together with No. 37, Calmar, Inc. v. Cook Chemical Co., and No. 43, Colgate-Palmolive Co. v. Cook Chemical Co., also on certiorari to the same court.

In No. 11 petitioners sued for infringement of a patent [illegible]

Appeal Brief for App. No

BITTNER ARTERIOVENOUS
Subcutaneous with ePTFE

Ri
of

EXPANDED POLYTETRAFLUOROETHYLENE (PTFE) SUBCUTANEOUS ARTERIOVENOUS CONDUIT: AN IMPROVED VASCULAR ACCESS FOR CHRONIC HEMODIALYSIS

L. D. Baker, Jr., J. M. Johnson, and D. Goldfarb

Recent experience with expanded polytetrafluoroethylene (PTFE) has demonstrated that a specific form of this material functions extremely well as a small artery prosthesis[1]. The basic ultrastructure of expanded PTFE is illustrated in Figure 1. Spindle-shaped PTFE nodes are oriented radially in the graft wall and these nodes are interconnected by fine fibrils. This node-fibril arrangement forms a type of lattice-work, and the distance between the nodes as well as the node diameter can be varied in the fabrication process. The specific form of this [illegible] wall thickness of between 0.3 and 0.6 mm, and 4) a density of 0.3 Gm/ml. Histological evaluation of these grafts revealed a thin neointima with flattened [illegible] cells facing the bloodstream, along with complete [illegible] fibrous tissue ingrowth and [illegible].

With the early clinical success of expanded PTFE as a femoral-popliteal artery bypass graft[2], we then considered the use of this material as a subcutaneous A-V conduit for chronic hemodialysis.

Prior to any clinical trial, however, several questions needed to be answered:

[illegible]

[illegible] of bleeding?

2) Would clot propagation at the puncture site lead to obstruction of the graft?

3) Would infection of the prosthetic [illegible] become a problem?

MATERIALS AND METHODS

Experimental. Seven grafts of expanded PTFE were then inserted into dogs as loop fistulas between the [illegible] artery and common femoral vein. Over the following [illegible] [illegible] These catheters were inserted percutaneously into the graft, and blood was returned to the animal through a [illegible] [illegible] grossly and histologically.

Clinical. [illegible] Phoenix, Arizona have been dialyzed using the expanded PTFE subcutaneous A-V conduit (Table I). Forty-three of these patients are male and 29 female. The ages of these patients range from 12 to 79 yrs, with a mean age of 46 yrs. Our preferred method of placement has been what we term the straight forearm graft, which is an anastomosis of the graft to the distal radial artery and to the cephalic vein near the antecubital fossa. If, however, the radial artery is not satisfactory either due [illegible] in the forearm between the brachial artery and cephalic vein. If access sites are not available in the upper extremities, then we have implanted these grafts in the thigh, either as a straight graft between the superficial femoral artery and common femoral vein, or as a [illegible] the common femoral artery and common femoral vein.

We have placed a total of 84 grafts in these 72 patients with 48 in the straight forearm position, 10 as forearm loops, [illegible] straight [illegible] the brachial artery at the antecubital fossa to the cephalic vein in the delto-pectoral groove. The majority of these grafts have been 8 mm in diameter, with 10 being 6 mm in diameter. Most of these grafts have been used within 8 days of implantation and several have been employed within [illegible]. The period of [illegible] has ranged from 4 to 60 wks.

TABLE I

EXPERIENCE WITH PTFE A-V FISTULAS

No. of Patients	[illegible]
Male	43
Female	29
No. of Grafts	84
Forearm, straight	48
Forearm, loop	10
Thigh, straight	6
Thigh, loop	13
Arm, straight	1
Age Distribution (yrs)	
10-19	1
20-29	11
30-39	15
40-49	13
50-59	19
60-69	11
70-79	4

From the Arizona State University-St. Joseph's Hospital Biomedical Engineering Research and Education Program, and Good Samaritan Hospital, Phoenix, Arizona.

Supported in part by The Robert and Irene Flinn Foundation.

[illegible] graft, International [illegible] Research Associates, Inc., 4209 South 36th Place, Phoenix, Arizona.